K100254

SECTION 5: 510(k) SUMMARY

Submitter:
Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

MAY 28 2010

Contact:
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Date of preparation: January 27, 2010

Name of device:
Trade/Proprietary Name: Reprocessed CS Bi-Directional Diagnostic Electrophysiology Catheter
Classification Name: Electrode recording catheter or electrode recording probe

Predicate Device	**510(k) Title**	**Manufacturer**
K050877	Coronary Sinus Deflectable Mapping Catheter	Biosense Webster, Inc.

Device description:
The reprocessed Biosense Webster® Coronary Sinus (CS) EZ STEER™ Diagnostic Electrophysiology (EP) Catheter (hereinafter CS Bi-Directional Diagnostic EP Catheter) is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The device is a 7FR catheter with a usable length of 115 cm. The catheter has a high-torque shaft with a braided bi-directional deflectable tip section containing platinum electrodes that can be used for recording and stimulation. Two asymmetric curve types, DF and FJ, are available providing two 180° opposed, single plane curves.

The rocker lever located on the handpiece is used to deflect the tip section. A Friction Control Knob is located on the opposite side of the rocker lever and can be rotated clockwise to lock both the tip curve and rocker lever in place. The high torque shaft allows the plane of the curved tip to rotate, enabling accurate positioning of the catheter tip at the preferred site.

Indications for Use:
The Reprocessed CS Bi-Directional Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

Technological characteristics:
The design, materials, and intended use of Reprocessed CS Bi-Directional Diagnostic EP Catheters are identical to the

predicate devices. The mechanism of action of Reprocessed CS Bi-Directional Diagnostic EP Catheters is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions' reprocessing of CS Bi-Directional Diagnostic EP Catheters includes removal of adherent visible soil and decontamination. Each individual CS Bi-Directional Diagnostic EP Catheter is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of reprocessed electrophysiology catheters. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that reprocessed electrophysiology catheters perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed CS Bi-Directional Diagnostic EP Catheter) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 2 8 2010

Ascent Healthcare Solutions
c/o Ms. Amanda Babcock
Senior Regulatory Affairs Specialist,
10232 South 51st Street
Phoenix, AZ 85044

Re: K100254
Reprocessed Electrophysiology Catheters (See Enclosed List)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: NLH
Dated: May 19, 2010
Received: May 21, 2010

Dear: Ms. Babcock;

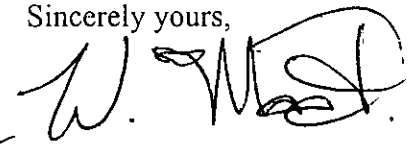
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Models Found SE:

Item No.	Description		French Size			Insertion Length	Curve Type
BD710FJ282RTS	Biosense Webster CS Bi-Directional Diagnostic EP Catheter		7Fr			115 cm	B-directional; J curve with a 10.2 cm deflectable span length
BD710DF282RTS	Biosense Webster CS Bi-Directional Diagnostic EP Catheter		7Fr			115 cm	Bi-directional; D curve with 6.4 cm deflectable span length

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

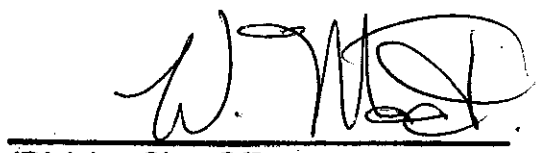
Device Name: Reprocessed Coronary Sinus Bi-Directional Diagnostic Electrophysiology Catheter

Indications For Use:
The Reprocessed CS Bi-Directional Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100254